United States Court of Appeals

for the Second Circuit

BRIEF FOR APPELLANT

76-6135

To be argued by
MILTON A. BASS

In The

United States Court of Appeals

For The Second Circuit

THE NATIONAL NUTRITIONAL FOODS ASSOCIATION and SOLGAR, CO., INC.,

Plaintiffs-Appellants,

vs.

F. DAVID MATHEWS, Secretary of Health, Education and Welfare and ALEXANDER M. SCHMIDT, Commissioner of Food and Drugs,

Defendants-Appellees.

On Appeal from the United States District Court for the Southern District of New York.

BRIEF FOR PLAINTIFFS-APPELLANTS

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BRIEF FOR PLAINTIFFS-APPELLANTS

INTRODUCTION

Plaintiffs-appellants appeal to this Court from an order of the United States District Court for the Southern District of New York, entered by the Honorable Marvin E. Frankel on July 2, 1976. This appeal, after remand, is made necessary by reason of the District Court's failure to comply with the decisions of this Court in *National Nutritional Foods Association v. Food and Drug Administration*, 504 F.2d 761 (2d Cir. 1974) and *National Nutritional Foods Association v. Weinberger*, 512 F.2d 688 (2d Cir. 1975).

The decision by Judge Frankel from which this appeal is taken was his second dismissal of plaintiffs' complaint. The first dismissal [NNFA v. Weinberger, 376 F. Supp. 142 (S.D.N.Y. 1974)] was vacated and remanded by this Court for the purpose of conducting an *Overton*-type hearing in accordance with applicable guidelines laid down by this Court as to both the law and the facts.

The remand by the District Court was for the purpose of determining whether the agency had properly classified certain vitamin A and D products as drugs, as a matter of law, within the statutory definition contained in the Federal Food, Drug, and Cosmetic Act. This Court held out the possibility that the previously unsubmitted complete administrative record might have provided a basis for the agency's classification. Appellants respectfully submit that the District Court failed to comply with this Court's mandate both as to the substantive law and the appropriate procedures. In addition, the ruling of the District Court does not take into account newly enacted legislation dealing specifically with subject matter of the instant case.[1] Although the agency had a second opportunity, no new record material was submitted which would support the agency's action herein.

The instant appeal presents for decision important legal questions arising under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §301 *et seq.* as well as the Administrative Procedure Act, 5 U.S.C. §500 *et seq.* For the reasons set forth, *infra*, it is respectfully requested that the decision of the District Court be reversed.

STATEMENT OF ISSUES PRESENTED

1. Whether defendants-appellees have demonstrated by objective evidence that all vitamin A and D products in excess of 10,000 and 400 I.U. respectively were intended by all vendors for therapeutic use.

2. Whether the District Court complied with the requirements for an *Overton*-type hearing in accordance with the directions of this Court for the conduct of the remand proceeding.

STATEMENT OF THE CASE

This Court is fully familiar with the background and history of this lengthy litigation.[2] Nevertheless, for the purposes of the instant appeal, it is necessary to detail to a limited extent the factual and legal history of this case so that the error of the District Court with respect to the remand be clearly set forth. Involved is not only the specific controversy concerning vitamins A and D, but also its

1. Vitamin and Mineral Bill, included as Title 5 of Public Law 94-278 enacted April 22, 1976, 90 Stat. 401 at 410, adding a new §411 to the Federal Food, Drug, and Cosmetic Act, codified at 21 U.S.C. §350 set forth in the Addendum at A5.

2. The Food and Drug Administration's efforts to directly regulate vitamins and minerals has given rise to a series of cases, all involving the National Nutritional Foods Association.

interrelationship with the more general regulatory effort by the Food and Drug Administration concerning all vitamins and minerals.

A. Factual Background

The dispute concerning vitamins A and D must be viewed in terms of the general context of the controversy as to the role of vitamins in human nutrition. This philosophical dispute was highlighted at lengthy hearings before the agency. For many years leading experts on nutrition have differed widely as to the extent of, and need for, vitamin supplementation (JA24a, 54a, 92a-95a, 184a, 329a, 585a).[3]

It can fairly be said that the position of the Food and Drug Administration was and continues to be adverse to those who have suggested that greater amounts of vitamins and minerals may be required for daily *optimum* nutrition and health.

The Food and Drug Administration has sought to establish as definitive certain recommendations of the Food Nutrition Board of NAS/NRC with respect to daily vitamin intakes. With respect to vitamin A, for example, Recommended Daily Allowances (RDA's) are 5,000 I.U. for adults with lesser amounts recommended for various non-adult categories. On the other hand, many leading nutritionists, including, for example, Nobel Prize winner, Dr. Linus Pauling, contend that there is evidence suggesting that the optimum daily intake of vitamin A for adults is properly set at 25,000 I.U. (JA184a). The philosophy behind the general vitamin regulations was that products should be restricted to quantities which comport with the conservative nutritional views of the FDA.

B. History of the Vitamin A and D Regulations

The Commissioner originally made no explanation for either a factual or legal basis for classifying *all* such products as drugs above a proposed prescription level of 10,000 and 400 I.U. In fact, the Commissioner stated that the agency action was to apply even to products expressly intended for distribution as dietary supplements.

> "[F]or any vitamin A preparation *intended for distribution as a dietary supplement* or as an over-the-counter drug, the recommended daily dosage shall not exceed 10,000 I.U. of vitamin A." (Emphasis added.) 37 F.R. 26619, Col. 1 (Dec. 14, 1972) (JA36a).

3. All "JA" references are to the Joint Appendix.

> "[T]he recommended daily dosage of any vitamin D preparation *marketed as a special* dietary food, or as a over-the-counter drug shall not exceed 400 i.u." (Emphasis added.) *Id.* Col. 2.

The proposal made no reference to testimony as to vitamin products, including vitamins A and D which had been adduced before the Commissioner as part of lengthy public hearings in connection with then pending revision of regulations for foods for special dietary use. On January 19, 1973, however, the same agency published in the Federal Register a tentative final order which was the end-product of the aforementioned administrative proceedings with respect to all vitamin products. The proposal contained a specific provision classifying as "drugs" all vitamin products, including vitamins A and D in potencies exceeding certain percentages of newly established U.S. Recommended Daily Allowances (U.S. RDA). The provision was contained in a proposed 21 C.F.R. §125.1(h) as follows:

> "Any product containing more than the upper limit of the U.S. RDA per serving (or where appropriate), per daily recommended daily quantity of a vitamin or mineral as specified in §80.1(f)(1) of this chapter is a drug . . . ." 38 F.R. 2150, Col. 1 (Jan. 19, 1973).

Finally, on August 2, 1973, the agency promulgated both the general vitamin regulations, including the purported drug definition as well as the instant vitamin A and D Statement of Policy. On that date, the agency advanced for the *first* time its rationale that vitamin products could be considered drugs because they were sold in quantities exceeding the U.S. RDA's. The agency claimed that there was no food or nutritional purpose for vitamin products beyond the conservative levels in the U.S. RDA's and that therefore the products were only appropriate for therapeutic purposes and would therefore be classified as drugs. See 38 F.R. 20710, Col. 2 (August 2, 1974).

In response to similar objections received as to drug status in connection with the instant Statement of Policy, the comments accompanying the final agency action herein expressly relied on the general vitamin regulations as support for drug classification and advanced the identical theory for vitamins A and D:

> "The question regarding whether a vitamin is a food or drug generated considerable discussion. The tentative and final orders promulgating §§ 80.1,

> 125.1, and 125.3 (21 CFR 80.1, 125.1 and 125.3), published in the January 19, 1973 Federal Register (38 F.R. 2143, 2152) and elsewhere in this issue of the Federal Register discuss this matter in detail. The Commissioner concludes, on the basis of all the available evidence, that vitamins between the upper and lower limits as specified in §80.1 are adequate for all known nutritional needs for normal individuals and that nutrients at these levels are dietary supplements which are foods for special dietary use . . . .[I]ntake of vitamins at levels exceeding the upper limits as specified in §80.1 are therefore appropriate only for therapeutic purposes and thus are properly classed as drugs." 38 F.R. 20723.

It is, therefore crystal clear that the agency's only expressed basis for drug definition in the instant proceeding were the levels for drug status established in the general vitamin regulations, *i.e.*, anything in excess of the levels in §80.1 which for vitamins A and D were 8,000 and 400 I.U. respectively. No other rationale was advanced by the agency. This interrelationship and unity of regulatory approach was further made clear by the Commissioner as follows:

> "One comment from a manufacturer stated that the proposal conflicts with the limits for vitamin A established by the food labeling regulations published in the January 19, 1973 Federal Register (38 FR2124) The Commissioner finds no conflict between this drug regulation and the food regulations. Those vitamin A preparations within the ranges specified in §80.1 are considered foods and must be labeled as dietary supplements. Those preparations containing vitamin A in excess of the upper limit of these ranges, but less than the proposed prescription drug level, are OTC drugs. Those preparations containing in excess of 10,000 IU of vitamin A per dosage unit are prescription drugs." 38 F.R. 20725.

On August 15, 1974, the United States Court of Appeals for the Second Circuit, as part of a lengthy opinion by Judge Friendly, invalidated the above-discussed rationale for the agency's drug definition in §125.1(h). See *NNFA v. FDA,* 504 F.2d 761, 788-789 (2d Cir. 1974). In light of the interrelationship of the agency's attempted drug classification in both regulations, Judge Friendly's opinion necessarily cast grave doubt (if not a conclusive

determination), as to the continued viability of the drug classification for vitamins A and D herein. This landmark decision expressly took note of the consequence that the invalidation of the drug definition would have on the issue of prescription status for vitamins and minerals. 504 F.2d at 788-789. The Court noted that even aside from the evidence, the attempted definition was beyond the agency's authority in the statute. 504 F.2d at 789, n.35. This Court also expressly noted its disagreement with the prior decision of Judge Frankel herein on the same issue. 504 F.2d 788, n. 33.

As noted by Judge Mansfield in remanding to the District Court:

> "Applying the foregoing principles here, a serious question is raised as to whether the Commissioner, in concluding that the higher level dosage forms of Vitamins A and D are 'drugs,' acted 'in accordance with law,' as that phrase is used in 5 U.S.C. §706(2)(A)." *NNFA v. Weinberger, supra*. 512 F.2d at 701.

C. The Court of Appeals' Ruling With Respect To Drug Classification

In *NNFA v. FDA, supra,* Judge Friendly struck down the agency's attempted drug classification for all vitamins and minerals exceeding the established U.S. RDA levels. The statutory definition for a drug is contained in §201(g) [21 U.S.C. §321(g)] as follows:

> "The term 'drug' means (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clauses (A), (B), or (C) of this paragraph; but does not include devices or their components, parts, or accessories."

Judge Friendly's decision holds at 504 F.2d 789:

"The FDA's decision to handle as drugs all vitamin and mineral products in excess of the upper limits of the U.S. RDA's rested essentially on the thought expressed in paragraph 12 of the preamble to Part 125, 38 F.R. 20710 (1973): 'The hearing record discloses no known food or nutrition use of nutrients at such high levels, and no such uses were shown in the exceptions.' We believe that this mischaracterizes the record. As will emerge more fully in the next section of the opinion, dealing with the RDA's as a basis for the upper limits in the standards of identity, a significant number of persons have indisputable nutritional need for potencies exceeding the upper limits; in particular, and by no means exclusively, this includes the large number of women taking oral contraceptives. In light of this, it cannot be said even as an objective matter that a given bottle of pills, each containing more than the upper limit of one or more nutrients, is not being used for nutritional purposes.

A fortiori it follows that the vendor of such a product can in good faith intend it for nontherapeutic use. Section 201(g)(1)(B) makes the vendor's intent the crucial element in the definition of 'drug' here at issue, *see also* S. Rep. No. 361, *supra,* in Dunn at 240, and the cases consistently have read that language for its plain meaning. While we agree that a factfinder should be free to pierce all of a manufacturer's subjective claims of intent and even his misleadingly 'nutritional' labels to find actual therapeutic intent on the basis of objective evidence in a proper case, such objective evidence would need to consist of something more than demonstrated uselessness as a food for most people. We therefore hold that §125.1(h) is invalid.[35]

[35] While we thus reach this holding as a question of insufficient evidence, we must agree with petitioners that *an administrative interpretation in such direct conflict with a legislative definition might also be invalidated on the ground of exceeding the agency's statutory authority."* (Emphasis added.)

In this connection, it is useful to note that the legislative history cited by Judge Friendly clearly shows that the manufacturer by his actual intent and label representations can and does determine the appropriate classification of the product as a food or a drug.

> "The use to which the product is to be put will determine the category into which it will fall. If it is to be used only as a food it will come within the definition of food and none other. If it contains nutritive ingredients but is sold for drug use only, as clearly shown by the label and advertising, it will come within the definition of drugs, but not that of food. If it is sold to be used both as a food and for the prevention or treatment of disease it would satisfy both definitions and be subject to the substantive requirements for both. *The manufacturer of the article, through his representation in connection with its role, can determine the use to which the article is to be put.*" S.Rep. No. 361, 74th Cong., 1st Sess. 4 (1935). (Emphasis added.)[4]

Thus, in accordance with the foregoing, a drug classification requires objective evidence of actual therapeutic intent in a proper case on the part of the manufacturer. Without such evidence, no drug classification can legitimately be found or applied. Similarly, Judge Mansfield expressly recognized these requirements. After noting that the Commissioner with respect to vitamins A and D had relied generally and heavily on the now invalidated general drug definitions of the vitamin regulations, he found:

> "As Judge Friendly said, 'demonstrated uselessness as a food for most people' would not automatically establish that the higher levels qualify as a 'drug' within the definition in §201(g)(1). The statute requires a finding of intent that the product be used for therapeutic purposes, *and the Commissioner made no such finding.*" (Emphasis added.) *NNFA v. Weinberger, supra,* 512 F.2d at 703.

This Court, in what can only be described as the exercise of abundant caution, gave the agency the opportunity to show on the remand that the Commissioner had additional record material before him which might support the attempted drug classification

4. Significantly, the administrative agency herein was attempting to classify *all* vitamin A and D products sold by all manufacturers, irrespective of any representations made in connection with the sale of 10,000 and 400 I.U. respectively.

within the criteria laid down by the decisions of this Court. As will be discussed, *infra,* the District Court failed to specifically address these criteria and the agency failed to submit any additional record material which supported the classification.

In sum, the record which is now before this Court on appeal after remand is, substantively speaking, the same record which, in effect, this Court previously held insufficient to uphold the regulations.

D. The Remand Proceedings

In response to the decision herein, remanding proceedings to the District Court, the Commissioner of Food and Drugs submitted an affidavit, dated the 21st day of March, 1975, which sought to set forth the basis on which the Commissioner had classified vitamins A and D, at above 10,000 and 400 I.U. respectively, as drugs in the original regulations at issue. The Commissioner's affidavit did not explain his own prior statement in the Federal Register in which he had expressly relied on the now invalidated §125.1(h) drug classification. In fact, the affidavit made no mention of the earlier and only rationale expressed by the affidavit for drug classification. Instead, the Commissioner began by noting:

> "Speaking frankly, I believe we did not set forth a more detailed rationale for the drug status of these high dosage preparations in the Federal Register of August 2, 1973, because we felt the classification was so obviously proper." (JA318a, 379a).

The Commissioner proceeded to explain to the "best of his memory" as to why he had concluded in August of 1973 that the products in question were classified as drugs within the meaning of the statute. The affidavit did not address itself to the criteria set forth by the Court of Appeals, did not explain the selection of 10,000 and 400 I.U. respectively as appropriate levels for drug classification and, moreover, purported to base his drug classification on various documents which were submitted to the Court upon the remand, but which in fact were not even available at the time the regulations were originally promulgated. (E.g. JA337a).

On September 4, 1975, Judge Frankel called a conference in his chambers to discuss the remand proceedings. At this conference, Judge Frankel directed that:

1. The Commissioner submit a revised affidavit which omits any references to material which was not available to the Commissioner at the time of the promulgation of the regulations.

2. That in light of the affidavit of the Commissioner it would be necessary to have a hearing and that he should be examined in connection with the remand proceeding as to the validity of the drug classification.

3. The agency was directed to compile the whole record by adding the materials which had not previously been placed before the District Court and the Court of Appeals so that evidence or a basis for drug classification could be determined and so that an analysis of the supplemented record could be made by the parties in this regard.

The Commissioner of Food and Drugs did submit a revised affidavit (JA377a), dated February 13, 1976, which basically followed the outlines of the first affidavit except that it omitted some of the extra record material included in the first affidavit, and despite the express direction of the Court, sought fit to include other material which had not been available at the time that the regulations were originally promulgated on August 2, 1973. The agency refused however to submit any additional documents as part of the record (JA373a).

On May 28, 1976, Judge Frankel scheduled another conference, to further consider the remand proceedings (JA516a). At this session, Judge Frankel reversed himself as to the question of holding a hearing and requiring an examination of the Commissioner as to his basis for drug classification (JA532a). In light of this development, appellants requested that the Commissioner's affidavit be stricken from the record because an examination was needed to point out the error in the Commissioner's reasoning.[5]

The District Court declined to allow cross-examination and declined to strike the affidavit. As will be noted herein, the affidavit was, in any event, insufficient to support the drug classification.

At the conference, attorneys for the government for the first time offered to produce some materials which "arguably" could be made part of the record, but declined to produce certain documents on the ground of privilege which consisted of early drafts of the proposed regulation and intra-agency memoranda (JA518a-520a). An additional conference was held on June 1, 1976 where

5. "MR. BASS: We can't attack it, sir, if we can't examine him.

THE COURT: If that is the only way you can attack it, you are helpless, I realize that." (JA534a).

government counsel submitted various folders containing a few papers of additional record material, as well as one folder which was handed up to the Court with respect to which the privilege was raised (JA554a). On July 2, 1976, Judge Frankel rendered an opinion in which he refused to allow an examination of the Commissioner, refused plaintiffs' request for the production of the allegedly privileged documents, and, once again, dismissed the complaint (JA565a).

E. The Newly Enacted Statute Concerning Vitamins and Minerals

An extremely important development in the instant proceeding came with the enactment on April 22, 1976, in the middle of the remand proceeding, of a new statute by the Congress which expressly directs itself, in part, to the question of the permissible scope of drug classification herein.

Congress added a new §411 to the Federal Food, Drug, and Cosmetic Act which provides in relevant part:

> "'(B) the Secretary may not classify any natural or synthetic vitamin or mineral (or combination thereof) as a drug solely because it exceeds the level of potency which the Secretary determines is nutritionally rational or useful; . . ." 21 U.S.C. §350 (a)(1)(B).

This statute was directly aimed at the regulatory efforts of the Food and Drug Administration with respect to attempted drug classification for vitamins and minerals. The statute expressly negates the prior rationale which had been advanced by the agency for drug classification herein, to wit, the Commissioner's view that there was allegedly no recognized nutritional purpose for vitamins and minerals in excess of the U.S. RDA level.

In enacting this statute, the Congress was, of course, codifying the prior ruling of this Court which invalidated the general drug classification. The statute, therefore, makes it crystal clear that the Commissioner is not permitted to impose his views on nutrition by applying the drug classification to products which do not conform to those views. In so doing, Congress struck down, as did this Court, the only rationale which had previously been expressed by the agency to support drug classification in this proceeding.

The legislative history of the new statute shows that Congress, while striking down one element as a basis for drug classification,

reaffirmed the earlier understanding as to the requirements for drug classification. Conference Report accompanying H.R. 7988, House of Representatives, 94th Congress, 2nd Session, Report No. 94-1005, page 28. (Copy of the relevant pages of the Report are set forth at JA613a).

> "Except as specifically provided, the conference substitute does not alter the drug or food provisions of the Federal Food, Drug, and Cosmetic Act. If a product containing vitamins, minerals or other ingredients is a drug within the meaning of section 201(g) of the Act, the Secretary may, with respect to such product, exercise his authority under Chapter V of the Act. For example, the Secretary may bring an action for misbranding of a product which purports to be or is represented as a drug (within the meaning of section 201(g) of the Act) if its labeling fails to bear adequate directions for its purported use or for the use for which it is represented (within the meaning of section 502(f)(1) of the Act)." (JA622a).

Congress also expressly took note of the limitations involved in the agency's authority to classify items as prescription drugs.

> "The Secretary also has the authority to regulate the composition and potency of a product subject to the provisions of the conference substitute on the basis of safety. *If a high potency preparation of a vitamin or mineral is a drug as defined by section 201(g) of the Act* and the Secretary determines that within the meaning of section 503(b) of the Act, it is not safe for use except under the supervision of a physician, such a high potency preparation is subject to regulation as a prescription drug under the Act." (Emphasis added.) (JA622a).

ARGUMENT

POINT I

THE AGENCY HAS COMPLETELY FAILED TO DEMONSTRATE THAT ALL VITAMIN A AND D PRODUCTS, IN EXCESS OF 10,000 and 400 I.U. RESPECTIVELY, WERE OBJECTIVELY INTENDED BY THEIR VENDORS FOR THERAPEUTIC USE.

The scope of the remand to the District Court and, consequently, the instant appeal, was and is limited to determining whether, as a matter of statutory construction, there was any basis in the record before the agency for regulating *all* vitamin A and D products above 10,000 and 400 I.U. respectively as "drugs" under the Act. It has been conceded throughout that a product cannot be classified as a prescription drug if it is not a "drug" under the statute. In the remand proceedings, the agency failed to show any basis for automatically classifying all of these products as drugs. There was, in fact, a crucial lack of any evidence whatsoever in the record to support the agency, on the fundamental question of the objective intent of the manufacturers who marketed vitamin A and D products in these quantities.

A. The True Significance of the Food-Drug Distinction: Toxicity Is Not An Issue.

It is important to clearly set forth that the distinction between whether products are classified as drugs or foods, relates not to any considerations of safety or harm to the consumer, but instead involves different regulatory standards and procedures which would come into operation in determining whether a particular product could be sold. For example, Judge Friendly in his earlier decision invalidating the agency's general drug definition, expressly recognizes this would have the effect of precluding a "prescription drug" classification. *NNFA v. FDA,* 504 F.2d at 788.

Toxicity is not an element in determining whether or not a product is a drug within the definition contained in the Federal Food, Drug, and Cosmetic Act. First, the very language of the statute, as contained in §201(g) [21 U.S.C. §321(g)] makes it clear that toxicity is not a factor in the drug definition. There is absolutley no reference to toxicity in any of the various elements of drug classification.[6]

6. No case has ever been cited or found where in the entire history of the statute a product has been classified as a drug on the basis of alleged toxicity. Under the statute, the (Cont'd)

Secondly, the structure of the statute clearly indicates different and separate statutory approaches for dealing with both toxic foods and toxic drugs. Under the statute, toxicity is an element to be considered in determining prescription status for drugs. On the other hand, the statute deals specifically and separately with protecting the public from toxic foods. If a food is toxic, it can't be sold. In fact, if toxicity would be a basis for converting a food into a "drug", there would be no need for the statutory provisions (§402, 21 U.S.C. §342) which provides for deeming toxic foods to be adulterated and misbranded and thereby subject to statutory enforcement remedies. Certainly, toxicity has no relationship to any of the statutory elements in terms of "intended use for the treatment of disease."[7]

The legislative history of the Federal Food, Drug, and Cosmetic Act clearly shows the congressional intent as to this drug definition.[8] This declaration of congressional intent is inconsistent with the approach attempted by the agency herein in seeking to classify *all* of a particular category of vitamins as drugs without any reference to a specific intended use.[9] The allegation, as we have here, that a particular product is toxic or may have toxic effects, has no relationship to the question of its intended use. If an allegedly toxic product is not intended for drug use, under the plain language of the statute, it is not a drug. This Court, in outlining the scope of the remand from the District Court, made no reference whatsoever to toxicity as a possible element in drug definition.

It is not surprising that toxicity is not an element in the statutory definition of the term "drug", since the statute itself makes specific provisions for dealing with foods which may be harmful to

(Cont'd)

question of the safety of some foods such as cyclamates, and Red Dye #2 (until recently found in such food items as beverages and maraschino cherries) has often arisen. None of them have ever been classified as drugs and where they have been removed from the marketplace, it has been exclusively under the food provisions of the statute.

7. It may be noted that one element of the drug definition relates to articles intended to "affect the structure or function of the body of man." Vitamins undoubtedly have such a function and so do almost all foods. It is for this reason that the statute specifically excepts foods from this element of the definition. If a product is sold as a food, it does not come within the drug definition, even though the product is intended to affect the structure or function of the body of man. This exception is necessary in order to give the statute practical utility. Otherwise, every food would be a drug and that clearly is not the statutory intent.

8. See discussion of legislative history which was cited with approval by this Court, *supra*, at p. 8 .

9. In fact, it was for this reason that this Court struck down the same agency's attempted rule for a general drug classification for all vitamin products. *NNFA v. FDA*, 504 F.2d 761 at 789 (2d Cir. 1974). It was this now invalidated regulation which formed the primary, if not only, basis for the original agency action herein.

human health. Under §402(a) of the Act [21 U.S.C. §342(a)] many detailed provisions are set forth with respect to foods which are deemed to be adulterated and thereby subject to all of the regulatory sanctions provided in the statute.

The approach under the Act is first to determine whether a product is a food or a drug in terms of its intended use, and thereafter to apply the appropriate standards for dealing with them. The instant regulations reverse this process by declaring in advance that *all* of the regulated vitamins and minerals are drugs without regard as to how they are intended to be used. This defeats the structure of the statute, as well as any common sense interpretation.

Appellants respectfully wish to point out to the Court that the position of the agency in the District Court, as well as here is inconsistent with the approach taken by the very same agency with respect to other vitamins and minerals which pose similar, if not identical questions. As noted earlier, the original philosophy beyond the general vitamin regulations promulgated by the same agency was to restrict the quantities of vitamins and minerals available to those listed in the now familiar U.S. RDA tables. A key element in this restriction was the general drug classification in 21 C.F.R. §125.1(h) which was invalidated by this Court.

In response to such invalidation, the agency abandoned the notion of restricting vitamin quantities per dosage unit for individual vitamins or minerals. As far as is relevant herein, the same Commissioner for the same agency noted in the Federal Register of Wednesday, May 28, 1975:

> "The Court ruled §125.1(h) to be invalid. This paragraph had provided that, except for certain specified and quite limited products, a vitamin/mineral product with a potency exceeding the limits set by §80.1 was necessarily a drug.
>
> The Court concluded that the hearing record did not show that there is no known food use of nutrients at such high levels.
>
> * * *
>
> The Commissioner has considered whether the record should be reopened to permit the admission of additional evidence on this matter. In view of the fact that the sole difference between the approach taken

> in §125.1(h) and the approach taken by the Court is that, pursuant to the Court's decision, these products will not be regulated under the law as foods rather than as over-the-counter (nonprescription) drugs, the Commissioner has concluded that no useful purpose would be served by pursuing this point as a general rule at this time." 40 F.R. 23246 Cols. 2 and 3.

Equally inconsistent is the agency's continued insistence on emphasizing the alleged unrecognized nutritional use for vitamins A and D above 10,000 and 400 I.U. respectively, as a basis for prohibition of their sale herein. The agency itself has enacted another regulation with respect to such products which takes a totally different approach. 21 C.F.R. §125.2(b)(5) deems misbranded a food product if its labeling represents:

> "That the food has dietary properties when such properties are of no significant value or need in human nutrition. Ingredients or products such as rutin, other bioflavonoids, para-aminobenzoic acid. inositol, and similar substances which have in the past been represented as having nutritional properties but which have not been shown to be essential to human nutrition may not be combined with vitamins and/or minerals, added to food labeled in accordance with this section, or otherwise used or represented in any way which states or implies nutritional benefit. *Ingredients or products of this type may be marketed* as individual products or mixtures thereof: *Provided,* That the possibility of nutritional, dietary or therapeutic value is not stated or implied. Examples of false or misleading statements or implications are:
>
> (i) Label statements to the effect that their need or usefulness in human nutrition has not been established.
>
> (ii) Lable statements which otherwise disclaim nutritional, dietary or therapeutic value."

In fact, even in the instant case, the Commissioner has recognized that the food provisions of the statute have relevance to the products at issue herein. In both of the affidavits submitted by the Commissioner, express recognition is taken of those provisions of the statute and their potential applicability (JA328a, 388a).

The affidavit, however, incorrectly supposes that application of the food standards would result in a prohibition on the sale of these products. Interpretation and application of the food provisions of the statute are not at issue herein and the Commissioner's judgment in that respect, without having complied with statutory standards and requirements for foods, is premature.

Judge Frankel in the District Court recognized this problem and all during a conference asked whether counsel for appellees would agree to strike the applicable paragraph from the Commissioner's affidavit.[10] The agency, however, did not withdraw that portion of the Commissioner's affidavit, but the formal decision of the District Court makes no reference whatsoever as regards this apparent effort to bypass the statutory requirements with respect to the regulation of foods.

The foregoing necessarily raises puzzling and troublesome questions which may properly be considered by this Court. There has been no explanation by the agency[11] for its apparent willingness to allow the food provisions of the Act to determine safety consideration as regards all vitamins and minerals other than vitamins A and D. Why should the agency insist on using a drug classification approach to vitamins A and D where the food

10.

> "[THE COURT:] I have a similar question. There is a suggestion in Commissioner Schmidt's paragraph 10 that this is all in some way a waste of time because if it is not a drug then it will turn out to be a food additive and we will all be at the same place.
>
> * * *
>
> I don't know why he has it in there, Miss Buchwald. If it were not a drug and it might be a food additive doesn't seem to cut any ice. If he has not properly defined it as a drug and some other day he calls it a food additive, we will worry about that.
>
> But why does he say, 'Judge, after all these years, you had better say it is a drug because otherwise I will call it a food additive.'
>
> * * *
>
> My untutored reaction to that paragraph was that it should be ignored or struck out because it is really an anticipatory side issue rather than a really helpful support for what the Commissioner has done, and I want you to tell me in that many words whether it does or doesn't support what he has done and, if it does, how. If you say it doesn't, I will ignore it." (Conference of May 28, 1976, pp. 22-23) (JA537a-538a).

11. None could be elicited from Commissioner Schmidt since cross-examination was not permitted by the District Court.

regulatory provisions, by the Commissioner's own statement, would be adequate if, in fact, there was a substantial question of safety at the regulated levels?

It is apparent that the agency's position herein in insisting on drug classification contrary to its own expressed policy with respect to other vitamins and minerals and other food substances can only be designed to short-circuit the statutory standards and procedures applicable to food products which would enable appellants to continue marketing safe quantities of vitamins A and D at levels above those banned by the instant regulations.

The agency itself has abandoned the general notion of preventing the sales of vitamins and minerals in quantities beyond that which the agency recognizes to be nutritionally useful. In fact, the Congress of the United States recently enacted legislation specifically prohibiting the Commissioner from classifying products as drugs on the basis of the Commissioner's views and the absence of nutritional usefulness.[12] In terms of protecting the public, the agency has adequate and effective tools to deal with food products which do in fact present a danger to the health of consumers. The use of potential toxicity and a drug classification in the instant regulations is, a relic of the now abandoned and congressionally and judicially invalidated prior agency rationale, which should be set aside by this Court.

B. The Remand Proceedings Produced No Basis For The Agency's Drug Classification.

The decision of this Court in *NNFA v. FDA,* 504 F.2d 761 (2d Cir. 1974) laid down the central guiding principle for determining when a product can be classified a drug under the Federal Food, Drug, and Cosmetic Act. Judge Friendly, in his decision noted:

> "Section 201(g)(1)(B) makes the vendor's intent the crucial element in the definition of 'drug' here at issue, *see also* S.Rep. No. 361, *supra,* in Dunn at 240, and the cases consistently have read that language for its plain meaning." (504 F.2d at 789).

This fundamental ruling, based on the express legislative history of the statute[13] requires that the focus on the validity of the instant regulation must necessarily center on whether or not the agency had a valid and proper basis for deciding that *all* vendors of vitamin A

12. Section 411(a)(1)(B), 21 U.S.C. §350(a)(1)(B). See discussion, *supra,* at p. 11.

13. See pages 6-9, *supra.*

and D products intended their products for drug use, when sold above the levels of 10,000 and 400 I.U. respectively. Judge Friendly further pointed out that a finding of intent for drug use must be based on objective evidence of the manufacturer's intent.

> "While we agree that a fact finder should be free to pierce all of a manufacturer's subjective claims of intent and even his misleadingly 'nutritional' labels to find actual therapeutic intent on the basis of objective evidence in a proper case, such objective evidence would need to consist of something more than demonstrated uselessness as a food for most people." *Id.* at 789.

It is now apparent that the agency's position in this proceeding is clearly untenable, in light of the invalidation of the drug definition in the general vitamin regulations. The instant vitamin A and D regulation had premised its entire theory of drug classification on the very definition which was invalidated by this Court. On the prior appeal, when this Court examined the criteria laid down by Judge Friendly with respect to the objective intent of the manufacturers for drug use, Judge Mansfield expressly stated:

> "The statute requires a finding of intent that a product be used for therapeutic purposes and *the Commissioner made no such finding." NNFA v. Weinberger,* 512 F.2d at 703. (Emphasis added.)

In the remand proceedings, the agency not only failed to show that it had any evidence of the objective intent of all manufacturers, but in fact retreated from the only position it had ever taken in this litigation on this crucial question. On the prior appeal, the government advanced the proposition that one company, Solgar Co., Inc., had been selling a 50,000 I.U. product as a drug bearing the labeling, "Take one tablet daily or as directed by a physician." Consequently, as part of the remand, this Court gave the Commissioner the opportunity to show that in promulgating the vitamin A and D regulations he had information indicating that vitamin A and D products were "labeled in such a way as to indicate a therapeutic use." Evidence of this sort, if it could have been found for manufactureres and vendors, might have provided the objective evidence of manufacturer's intent as required by the two decisions of this Court dealing with the drug definition.

In the District Court, however, it was firmly established that the very product to which the agency had referred had been discontinued approximately two years before the regulation had even been proposed, and that, moreover, the particular labeling suggesting usage in part, "as directed by a physician" in any event did not establish drug intent (JA448a-453a). Although Judge Frankel does not deal with this aspect in his opinion, it is important to point out that the Court below did deal with this matter as part of the remand proceedings.

> "THE COURT: . . . I want to ask this question:
>
> Is there any evidence in the record now before the Court, or was there any evidence in the record, wherever that was, before the Commissioner, of therapeutic claims made by the vendors of these high-potency formulations?
>
> I think the latest affidavit, unless I have skipped something, is devoid of any such assertions, and I want to know: Does the Commissioner make no claim that there was this kind of basis for his view or does he make such a claim?
>
> * * *
>
> MS. BUCHWALD: Your Honor, I believe at an earlier point in this litigation we had made reference to a product produced by Solgar, one of Mr. Bass' clients. I believe at a later point he came in with an affidavit saying they had discontinued that label.
>
> With respect to the promulgation of these regulations, and certainly as to Solgar, we withdraw any allegations that Mr. Bass' client was making a specific therapeutic claim.
>
> *I do not know, your Honor, of any evidence in the record making a specific reference to a label of a drug company making a therapeutic claim.*" (JA528a-530a). (Emphasis added.)

With respect to the central question before this Court, it is therefore undisputed that the Commissioner admittedly had no objective evidence of intent by any manufacturer to sell a product at issue for therapeutic purposes. Instead, the reasoning of the Commissioner is based on the premise that there has been

"widespread promotion to the laity" by other persons of these vitamin products for therapeutic purposes. With the Commissioner's affidavit, "devoid" of any objective evidence of intent, the only substitute offered is the following statement by the Commissioner:

> "*It seems to me* that the seller of such a high potency vitamin A or D preparation, which exceeds the levels recognized to be useful for ordinary nutritional supplementation, knows or *should know* that his product is *likely* to be used by purchasers hoping for some therapeutic benefit such as deliverance from cirrhosis, acne, psoriasis or arthritis. Frankly, it makes no more sense to me that someone should be able to say that such a product is not a drug because he subjectively wants to eat it as a food than it would to allow distributors of aspirin or LSD to avoid regulation of their products as drugs by saying that they have some customers who like the taste and who subjectively choose to regard these articles as foods." (JA381a). (Emphasis added.)

It is hard to imagine how any approach to this matter could be more subjective than the one advanced by the Commissioner. His entire premise is based not on any evidence of manufacturers' intent, but rather on his own personal impression,[14] unsupported by any evidence in the record, that the manufacturers ought to know that the product might be used for therapeutic purposes. In addition, leaving aside the rhetoric about LSD and aspirin, the Commissioner bases this approach on his notion that individuals should not be permitted to regard these vitamin products as foods because "they exceed the levels recognized to be useful for ordinary nutritional supplementation." This is in clear conflict with the express congressional mandate in the newly enacted Vitamin and Mineral Statute, directing the Commissioner not to classify vitamins or minerals as drugs on the basis of his finding or opinion that such products are not nutritionally useful. The public is entitled to use higher levels of vitamins A and D for food purposes as they see fit and manufacturers in good faith may sell such products in accordance with the desires of these consumers.[15]

Significantly, in terms of the objective intent of all or any manufacturers, the agency has failed to establish the absence of good faith in the promotion and sale of these products. It is the element of

14. Once again, it must be emphasized that the District Court did not allow cross-examination of the Commissioner in this or any other respect.

15. *Cf.* 21 C.F.R. §125.2(b)(5).

good faith which distinguishes the instant case from the extreme example of LSD and aspirin used by the Commissioner in his affidavit. In a proper case, the Commissioner would easily be able to demonstrate the absence of good faith on the part of any manufacturer who tried to sell LSD or aspirin as a food. In the alternative, the Commissioner could regulate such an attempt by recourse to the statutory provision concerning toxic foods. Neither of these has been done with respect to vitamins A and D in the instant case.

It is therefore evident that the agency has failed to come within the guidelines set down by Judge Friendly's decision of this Court, the subsequent decision of this Court as set forth in Judge Mansfield's opinion and, finally, the newly enacted congressional statute which expressly vacates the philosophical underpinnings which motivated this restrictive regulation. On this basis, the regulation clearly cannot stand.

C. The Agency Has Failed To Meet The Requirements Laid Down By This Court In Remanding To The District Court.

This Court, previously remanded to the District Court because the entire record had not previously been supplied by the agency, leaving open the possibility that the Commissioner might have had a basis in such additional record to explain why vitamin A and D products herein were summarily classified as drugs. As previously noted, this Court set down express criteria which could be considered in this regard. Unfortunately, the District Court, after quoting the language of this Court, did not substantially examine these criteria. It is respectfully submitted that considering the few possible reasons suggested by this Court, which potentially might have justified a drug classification, the agency has failed to establish any of them upon the remand.

The first possibility held open by this Court was that the Commissioner might have based his decision upon evidence in the record showing that vitamins A and D, specifically in dosage forms exceeding 10,000 I.U. and 400 I.U. respectively, were used exclusively for therapeutic purposes.[16]

16. After stating that the record was incomplete, Judge Mansfield noted:

> "It is conceivable for instance, that the Commissioner had before him information demonstrating that the higher dosage forms were used almost exclusively for therapeutic purposes. Measuring intent on an objective basis, as it must be, he may

(Cont'd)

The "almost exclusive use for therapeutic purposes" is important in terms of relating to the objective intent of *all* manufacturers. The record in this proceeding and specifically the affidavit of the Commissioner, completely failed to establish any basis or submit any evidence in the record, for a finding by the Commissioner as to the relative percentages sold for food purposes as opposed to any amounts used or sold for drug purposes. "Sale and use" in this context must be related to the reasons of the manufacturers and the public as opposed to the views of the Commissioner as to any possible nutritional value. The error of the District Court in this respect is clear because Judge Frankel's decision equates the purported absence of an officially recognized nutritional use above 10,000 I.U. and 400 I.U. for vitamins A and D, with the absence of any food use.[17] Food use for products is not determined by whether or not the Commissioner for Food and Drugs considers a product to be nutritionally useful. Consumers, in good faith, can take products for nutritional purposes in accordance with views and beliefs which differ from that of the Commissioner of Food and Drugs. The Commissioner in his affidavit totally ignored and fails to deal with the question of the manner in which these products were being used by the public in terms of nutritional use. This is not surprising since the Commissioner in his affidavit expressly rejects the right of consumers to make a decision for themselves as to nutritional usefulness above the conservative levels permitted by the agency (JA321a).

This approach represents a clear error and misconstruction of the decision of this Court. If there was any doubt whatsoever, it has since been removed by the newly enacted statute which expressly prescribes that drug classification is not to be based on a finding that the product in question does not comport with the Commissioner's views on nutrition. In effect, Congress, in the new vitamin and mineral statute, expressly legislated the right of consumers to receive vitamin and mineral products for food uses at levels above and beyond that which the Commissioner feels is appropriate. With all due respect, the affidavit of the Commissioner, as well as the decision of the District Court, completely missed the point in light of their emphasis on officially recognized nutritional needs.

(Cont'd)

> have concluded that in view of the extremely small percentage used for nutritional purposes Vitamins A and D at higher dosage levels were intended for use in the 'cure, mitigation, prevention or treatment of disease.'" 512 F.2d at 703.

17. The Commissioner's position is clearly in error, as a matter of law, as well as common understanding. The statutory definition of food does not depend on "nutritional usefulness." Many foods, such as soft drinks, cakes and even some breakfast cereals, do not have nutritional usefulness per se or in the quantities marketed.

As Judge Friendly noted:

> "[I]n light of the testimony as to particularly wide variations in philosophy concerning the optimal intake of vitamin C, we are not convinced as things stand that a consumer who believes a 500 milligram pill of vitamin C, a quantity now frequently sold, will maintain his optimal body stores should be required to purchase five or six pills of ninety milligrams each, at greatly enhanced cost." 504 F.2d at 783.

The Commissioner's affidavit fails to even mention or analyze the extent of variations in philosophy concerning the optimal intake of vitamins A and D. The same considerations applying to vitamin C, as indicated by Judge Friendly, should also apply here. Vitamins A and D, just like vitamin C, can legitimately be sold for food use in accordance with differing views as to optimal nutrition. Given the absence of any statement by the Commissioner or evidence in the record in this regard, it is clear that the agency did not and could not meet the criteria set forth by this Court in having even considered the extent to which the products involved were sold and used as foods. There was not, and in fact, could not be, any finding by the Commissioner that they were being used "almost exclusively" for non-food uses as required by the decision of this Court.

The failure of the District Court to allow cross-examination of the Commissioner makes it difficult to demonstrate the full extent to which the agency must have been aware of the differing views as to optimal nutrition concerning vitamin A and D and their legitimate food use.[18] Nevertheless, the record does contain affirmative evidence in this respect, of which the Commissioner should have been aware, and which both his affidavit and the decision of the District Court completely overlook. The comment submitted by Dr. Linus Pauling, previously referred to herein, expressly states:

> "The optimum intake of a vitamin is the intake that leads to the best of health. This optimum intake is probably different for different persons. The average value of the optimum intake of vitamin A for an

18. Since the agency did not give notice of its rationale for drug classification prior to the final promulgation of the regulations of August 2, 1973, it is not surprising that most comments submitted by the public did not focus on this aspect. There was no reason for the public to assume that the Commissioner would question the fact that these products were being sold and used in accordance with the differing philosophies as to proper nutrition. For this reason too, the instant regulation should be vacated since the public did not have adequate notice as to the reasons for the proposed regulations as required by the Administrative Procedure Act.

adult is not known. I estimate it to be about 25,000 IU per day." (JA184a).

* * *

"The Food and Drug Administration, in justice to the American people, could ethically restrict the non-prescription sale to tablets or capsules containing no more than 10,000 IU of vitamin A only if the FDA had convincing scientific evidence that the optimum daily intake for most people, leading to the best of health, were less than 10,000 IU. The Administration does not have such evidence. In fact, the existing evidence indicates that the optimum daily intake is greater than 10,000 IU. It would accordingly be wrong for the FDA to limit the sale of vitamin A in this way." (JA185a).

Similarly, it should be noted that the Commissioner was aware of the views of author and nutritionist Adelle Davis, who also recommended nutritional use for vitamins A and D in excess of the conservative levels set forth in the RDA's.

"The amount of vitamin A needed varies with your activities. People who work in bright or dim light use up more of this vitamin than those who work in moderate light.

* * *

No one knows the amount of vitamin A needed daily, and in fact, the requirement varies widely with individuals. The National Research Council recommends that adults receive 5,000 units of this vitamin every day, but this quantity is inadequate for persons whose occupation or recreation causes them to be exposed to bright light (which destroys vitamin A quickly) or to dim light, which causes it to be used rapidly.

* * *

Most adults, I believe, would profit by obtaining at least 25,000 units daily, especially if you drive a car at night. Vitamin A offers many advantages to health

aside from good vision." Vitamin A: The See Vitamin by Adelle Davis (JA585a-587a).[19]

The Commissioner himself in promulgating the regulations expressly noted that it was intended to cover products "intended for sale as dietary supplements"(JA36a). The record is clear and conclusive. The products in question were and can be sold legitimately for food use at safe levels for adults and the agency's insistence on classifying the products as drugs can only have the effect of interfering with the nutritional philosophy which underlies this bona fide use.[20]

Two other interrelated potential criteria were suggested by this Court's prior decision. Although the agency had expressly relied on the prior invalidated drug definition in promulgating the regulations, Judge Mansfield held out the possibility that the agency had given separate consideration for drug classification in terms of vitamin A and D, as distinguished from the drug classification in the general vitamin regulations.[21]

The Commissioner's affidavit submitted in the District Court fails to address any of these issues. First, the Commissioner does not assert that there was a separate consideration for drug classification,

19. In fact, it was this very article which was the only basis for the statement made by the Commissioner in originally proposing these regulations that "there was widespread promotion" to the public of these vitamins. It is ironic to note the curious course the agency proceedings have taken. The quotation from Adelle Davis' comments related solely and clearly to adults and her recommendation for the intake of 25,000 I.U. (which coincides with Dr. Paulings' views), was clearly directed in that context. The adverse reaction to Adelle Davis' statement came from the American Academy of Pediatrics whose concern is obviously not with adults but with children, to whom Adelle Davis' comments were not directed in the first place. The final irony is the promulgation of the regulation by the FDA, relying heavily on the statement of the American Academy of Pediatrics but making no distinction between children and adults.

It should also be noted that the entire concept of the FDA's general vitamin regulations is based on labeling for different age groups distinguishing between adults, children and infants and further distinguishing between the particular market among these categories, for which a vitamin and mineral supplement is intended. Yet, these distinctions did not carry over with respect to the instant regulation.

20. The most specific evidence in the record with respect to the manner in which consumers purchase these products and the approach manufacturers took in supplying consumer demands is set forth in the affidavit of Allen Skolnick submitted to refute the agency's prior position that Solgar Co. Inc. was making therapeutic claims for its products (JA448a).

21. "Furthermore, there are several differences between the proceeding before the *NNFA v. FDA* court and that here. As to vitamin A there is a difference between the upper level encountered in *NNFA v. FDA* (more than 8,000 IU) and that before us (more than 10,000 IU) . . . .Unlike §125.1(h), which declared on the basis of general reasoning that a broad range of vitamins and minerals are 'drugs' when vended in dosages exceeding their RDA's, the regulations here are directed specifically at two vitamins, A and D. This suggests that the Commissioner may have engaged in a more detailed and specific consideration of these vitamins than was apparent in the §125.1(h) proceeding." 512 F.2d 688 at 703 (1975).

which was separate and apart from the general drug definition. Thus, for vitamin D, the purported drug definitional level is the same 400 I.U. in both regulations. The Commissioner also failed to make any explanation as to why 10,000 I.U. of vitamin A could be a threshold level for drug definition even though the prior 8,000 I.U. threshold level had been invalidated by this Court. This failure to focus on the individual threshold levels in terms of drug classification is a further defect in the agency's position. The Commissioner's affidavit is replete with references to "high dosages" of the particular vitamins at issue. Nowhere is there a specific reference, nor any evidence, to demonstrate that 10,000 and 400 I.U. of these vitamins respectively are the specific levels at which the product is either sold used or intended for therapeutic use.[22] This deficiency carries over into the decision of the District Court which also does not tie in any of its analysis to the specific regulated levels, once again referring only to unspecified "high dosages."

Finally, this Court suggested the possibility that the Commissioner might have had evidence indicating that vitamins A and D at the regulated dosages were labeled in such a way as to indicate therapeutic use. As previously noted, however (*supra,* p. 19-20), the agency completely abandoned this contention on the remand below.

The agency on the remand completely failed to meet any of the criteria laid down by this Court as possible bases for drug classification. No evidence or rationale whatsoever was presented to show the extent, if at all, to which the products were sold for drug purposes as opposed to food purposes, at the crucial 10,000 and 400 I.U. levels. None was indicated to show any basis for determining that the manufacturers and vendors of these vitamin products intended them for therapeutic use and none was presented to show that the agency had in any way previously given a separate consideration for vitamin A and D drug classification, separate and apart from the attempted general drug definition for all vitamins.

The absence of any rationale by the agency in terms of the criteria laid down by the two decisions of this Court and the new statute enacted by Congress mandate the invalidation of the regulations at issue herein.

The agency's action in these terms must be characterized as "arbitrary, capricious and not in accordance with law."[23]

22. Cross-examination of the Commissioner might have elicited responses to some, if not all, of these questions.

23. See 504 F.2d at 789 note 35 and the newly enacted Vitamin-Mineral Statute, 21 U.S.C. §350(a)(1)(B).

Fundamentally, the agency began the regulatory drug approach on the wrong premise and with the idea that it would be able to restrict vitamin products and dosage levels which did not comport with the agency's view and nutritional philosophy. That approach can no longer stand and even the *post hoc* rationalizations by the agency herein have failed to establish a legitimate basis for drug classification for vitamins A and D at 10,000 and 400 I.U. respectively.

D. The District Court Rationale For Drug Classification Is Invalid.

The foregoing discussion clearly indicates the error made by the District Court in upholding the instant regulations upon the remand. After rejecting certain *post hoc* arguments presented by the agency (JA572a) Judge Frankel, without making specific reference to the criteria previously discussed, upheld the drug classification because of a combination of two factors: First, the alleged absence of recognized nutritional use for vitamins A and D above 10,000 and 400 I.U. and, second, the supposed finding of "widespread promotion" of unspecified "high dosage" preparations for the treatment of many diseases.

Significantly, the District Court's formulation completely avoids any reference to evidence as to the objective intent of *manufacturers* who sold the vitamin products in question. Moreover, each of the elements set forth by the Court is clearly erroneous. First, the District Court apparently confused the alleged absence of recognized nutritional use with an absence of food use. The fact that a product (or quantity thereof) does not have a "recognized" nutritional purpose does not mean that it can not be used for food purposes. As previously discussed, the statute does not make such a determination and many foods do not have a nutritional use. Reference has already been made (pp. 3, 24-26 , *supra*) to the differing philosophies of nutrition which indicate that higher potencies of vitamin A and D can be used by persons for food use in accordance with varying views as to optimum nutrition. The newly enacted Vitamin and Mineral Statute (21 U.S.C. §350(a)(1)(B)) was expressly designed to permit the sale of vitamin and mineral products even though the Commissioner does not accept these differing nutritional philosophies. Significantly, the District Court failed to even discuss the applicability of this statute, which was enacted on April 22, 1976.

Equally in error, is the District Court's effort to examine objective intent. Instead of looking for evidence with respect to all, any or even one manufacturer, the Court notes that "articles both in

the medical and popular press have advocated the taking of vitamin A and D in large quantities to cure such diverse ills from acne to night blindness."(JA577a). The only evidence of this "widespread" promotion in the record consists of a single article by Adelle Davis previously referred to (p. 24, *supra*) (JA585a). The article in fact specifically recommends that 25,000 units of vitamin A would be appropriate for most adults for *nutritional* purposes, while also indicating the utility of 50,000 units of vitamin A in connection with vitamin deficiency and night blindness (JA587a). The article referred to is, therefore, hardly support for the proposition that vitamin A (no reference at all is made to vitamin D) is recommended for therapeutic purposes at a level of 10,000 I.U. The Commissioner, in his affidavit, similarly avoids this issue by stating only that he has been aware of therapeutic uses for "high dosage" of vitamin A and D without any reference to the specific levels at which the vitamins have been used or advocated therapeutically. No attempt was made by the Commissioner or the District Court to tie in the alleged promotion for treatment of disease (or even the actual therapeutic use), with the crucial threshold levels of 10,000 and 400 I.U.[24]

In any event, the agency and the District Court once again did not take into account the legitimate and bona fide use of these products in accordance with differing nutritional philosophies. The unilateral and unsubstantiated references to "widespread promotion" of vitamins A and D is insufficient to establish the objective intent of any, and certainly not all, manufacturers.[25]

The second element of the District Court's inquiry as to "objective intent" consisted of a review of certain letter comments submitted by consumers to the agency which made reference to their desire to continue using these vitamins in connection with such conditions as hay fever and the prevention of colds (JA577a, 581a). The District Court's reliance on these letters must itself be characterized as a "*post hoc*" explanation by the Court itself. The Commissioner's

24. The District Court was definitely unclear as to the distinction between nutritional and drug use. The Court cited one article in the record with respect to vitamin A that there is a "general belief by the laity that vitamins improve health and increase resistance to infection." (JA580a, n. 10). This characterization clearly indicates nutritional use of vitamins for the general purpose of improving health. Yet, the District Court seemed to think that this was evidence of drug use.

25. For example, the agency concedely had evidence before it with respect to inclusion of vitamins A and D as part of multi-vitamin food supplements (*e.g.*, JA241a). Under the rationale of the agency all of the other ingredients would be for food use, while the vitamins A and D would be for drug purposes. There is no support in the record for such a bifurcation of intended use. It is apparent that the thrust of the agency regulation was directed at individual vitamin A and D products, although it encompasses also combination products such as the one referred to above.

lengthy affidavits make absolutely no reference to these letters and give no indication that they formed any basis for his decision.[26]

These letters can in any event, not be claimed as support for the agency's position. The "representative" letters set forth by Judge Frankel in the Appendix to his opinion indicate some usage of these vitamins, but at levels far in excess of those sought to be imposed herein. Once again, there is no connection between the levels of vitamins used by these consumers and the crucial levels of 10,000 and 400 I.U. which the Commissioner made subject to drug classification. Many of the letters set forth deal with vitamins other than those at issue herein. Moreover, almost all of them make reference to the use of vitamins for prophylaxis (*i.e.* preventive purposes). The latter function is clearly a nutritional use much in the same way that the importance of vitamin C in the diet is for its prevention of scurvy. By definition, the nutritional role of vitamins is to prevent the adverse effect of vitamin deficiency. The Commissioner in his own affidavit (JA317a) concedes that prophylactic use of vitamins is a "food" usage (JA323a).

The District Court was also unduly restrictive in selecting the letters set forth in the Appendix to its decision. Numerous other comments and letters sent by consumers show even more clearly the nutritional food use for these vitamins on the part of the public at levels far above the regulatory prohibition.[27] For example, a letter of Wayne D. Gilham, dated February 10, 1973, advised the agency:

> "I wish to protest your proposed maximum non-prescription potencies on vitamins A & D, as per your news release of December 13, 1972. I regularly take quantities of these vitamins in excess of your proposed limits, not as therapy for any disease under doctor's care, but merely as preventative measures to ensure adequate 'fuel' to function in this stressful world." Volume 28 of Administrative Record (JA588a).

If anything, the totality of these letters[28] demonstrate that a significant number of consumers do, in fact, use these products for food purposes despite the Commissioner's contrary philosophy.

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26. It is not surprising that the Commissioner did not rely on these letters since they uniformly suggest that vitamins A and D, even at truly high dosage levels are not toxic.

27. Representative samples of these letters taken from the Volumns 28 and 35, which were examined by Judge Frankel, are set forth at (JA588a-612a).

28. Many of the letters specifically advised the agency that the writers considered the products to be "foods" rather than "drugs." (See *e.g.*, (JA589a, 594a, 599a.)

It is respectfully submitted that the rationale of the District Court was clearly in error and that the order granting summary judgment be reversed, and that the instant regulations be invalidated.

POINT II

THE DISTRICT COURT ERRED IN THE CONDUCT OF THE OVERTON-TYPE REMAND PROCEEDING.

The foregoing discussion makes it clear that the remand proceedings produced no basis for classifying the products at issue as "drugs" within the meaning of the statute. This Court would therefore be justified in vacating the regulations on this basis without having to reach the procedural issues raised by the District Court's conduct of the remand proceedings.

Nevertheless, the issues raised are important in that they deal both with the specific conduct of *Overton*-type hearings, as well as the general nature and scope of judicial review under the now familiar "arbitrary, capricious or not in accordance with law" standard laid down by the courts. In these respects, the lower court seriously erred as to the proper scope and function of the remand proceedings. If, for any reason, the Court should not vacate the regulations, these procedural issues and their effect on the outcome below must be considered.

The District Court's error in this respect stemmed, at least in part, from its view that the remand proceeding was no more than a typical review of agency action, rather than one in which an *Overton*-type hearing was deemed necessary. Consequently, the lower court applied typical and routine standards towards the procedural issues raised in what truly must be considered an atypical case. In addition, the effect of the lower court's decision is to contract the scope of judicial review of rule-making to a point where litigants challenging agency action are confronted with virtually impossible and unfair burdens and disadvantages. In each case, the District Court departed from a wide body of case law which should have indicated the proper result. Were it not for the fact that the agency herein failed to present an even colorable argument as to drug classification, it is respectfully submitted that these procedural errors would necessarily have required a burdensome additional remand.

A. The District Court Erred in Refusing To Permit Cross-Examination of Commissioner Schmidt With Respect To The Affidavits Submitted By Him.

In an effort to stave off further inquiry, the Commissioner of Food and Drugs submitted a first and then a second revised affidavit purporting to explain the basis for drug classification herein. It is essential to keep in mind the background which necessitated the remand proceeding. Previously, the Commissioner of Food and Drugs had directly given as a sole explanation for drug classification, his reliance on the now invalidated general drug definition which the agency attempted in 21 C.F.R. §125.1(h). Despite this Court's invalidation of that rationale, the agency was given a "second bite of the apple" in terms of the remand for the purpose of submitting the additional record and giving a fuller explanation which might serve to justify the otherwise invalid regulations. Twice this Court had indicated its rejection of *post hoc* rationalizations by the agency in this regard. Even the District Court expressly recognized with respect to one of the arguments presented by the Commissioner below, that it was a *post hoc* rationalization and it was therefore rejected (JA572a).

Under these circumstances, the agency was necessarily under a heavy burden to come forth and fully explain the interrelationship between the general vitamin regulations and the attempted drug classification herein. At the very least, the Commissioner was duty bound to take cognizance of his prior rationale and explain its role in the decision-making process. Finally, given the history of the attempted drug classification, neither the courts nor appellants should have been expected to accept the Commissioner's latest attempted explanation without opportunity for the closest scrutiny. The agency failed to meet this burden.

Despite the above, the District Court found that there was "nothing so irregular or peculiar as to justify the expedient of having the agency head grilled on the witness stand" (JA568a). In *Citizens to Preserve Overton Park v. Volpe,* the Supreme Court of the United States expressly took note of the serious inadequacies of affidavits for the purpose of enabling judicial review under the "arbitrary, capricious or otherwise not in accordance with law" standard. 401 U.S. 402, 419-421 (1971). Here, however, the District Court assigned the greatest weight to this type of disfavored affidavit. This Court, however, has rejected this type of reliance by noting:

> "such affidavits are 'merely "post hoc" rationalizations' for administrative action, *and cannot be given great weight.*" (Emphasis added.) *Aguayo v. Richardson,* 473 F.2d 1090, 1103, n.20 (2d Cir. 1973).

Although the Supreme Court in *Overton Park,* as well as this Court in directing the remand herein, left open the precise scope of determining the nature of the supplementation which would be necessary, the District Court erred as a matter of law in determining this issue. Referring to the fact that the probing of the process behind administrative decisions, is rare, Judge Frankel took the position that "an Overton-type hearing is not an open invitation, much less a direction, to cast aside this familiar learning . . ." (JA567a). The error here is fundamental. An *Overton*-type hearing is the very case where probing of an agency's decision-making process is necessary because of some earlier failure in the administrative process. An *Overton*-type hearing is *the* proceeding which constitutes the hopefully rare case where the premises underlying formally published rules must be subjected to scrutiny beyond that which exists in the ordinary case. The District Court erred in interpreting the discretion granted by this Court as a mandate for abandoning the very purpose of an *Overton*-type hearing.

Appellants are at a loss to understand as to how the lower court found that the "niceties of the Administrative Procedure Act were nowhere neglected in this case." (JA568a). From the very outset, the administrative agency failed to give any rationale as to drug classification until after the regulations were promulgated. Thereafter, in both the general vitamin regulations, as well as herein, the agency attempted various *post hoc* rationalizations which were rejected by this Court. Finding that the record was incomplete, this Court remanded to correct the deficiency. It is, therefore, of the utmost significance that in conducting the remand proceedings, the District Court failed to allow examination of the Commissioner on the theory that there had been no procedural infirmities in the first place!

Judge Frankel had originally recognized the above by expressly directing at the conference in chambers on September 4, 1975 that an examination of the Commissioner be had in light of his affidavit.[29]

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29. Since the question of discretion is also involved, appellants respectfully note that the Court's decision makes no mention of the change in position by Judge Frankel. The only explanation is set forth in the record of the second conference as follows:

(Cont'd)

The rigid approach of the lower court in avoiding an examination of the Commissioner is contrary to the rule laid down by this Court. In *Schicke v. Romney,* 474 F.2d 309 (2d Cir. 1973), this Court was presented with a similar situation and in remanding noted:

> "In this connection it may be that the district court should allow plaintiffs the opportunity to pursue all reasonable means of discovery including the taking of depositions. However, we cannot delineate the precise limits of proper discovery on remand. We leave this to the district judge's discretion, *noting only that we see no objection to plaintiffs' deposing the Secretary if that should be necessary to a determination of whether the Secretary obeyed the statutory mandate* concerning the comprehensive plan. In any event, there must be full inquiry to ascertain the basis of the Secretary's action with reference to any comprehensive plan." *Id.* at 319. (Emphasis added.)

In the instant case, the district court allowed appellants no discovery whatsoever.

The proper scope of an *Overton*-type proceeding is quite logically suggested by the remand in the *Overton Park* case itself.

> "A short while after the decision of the Supreme Court came down on March 2, 1971, we met informally with counsel for the parties to discuss the future course of this case. . . . Counsel for the plaintiffs then stated that they would want to take some discovery depositions after the record was filed. Defendants objected to this, contending that the first inquiry should be to determine whether the Secretary's decision could be reviewed on the bare

(Cont'd)

> "I have brooded and brooded on that question and I believe I was wrong when I indicated that he ought to be called in to be examined . . . .
>
> I believe what he has submitted as his recollection of his views is not a fit subject for examination and cross examination any more than I think we ought to haul a Congressman in here and cross examine him about whether he really meant what he said or whether he actually was bribed to pass the Sherman Act.
>
> * * *
>
> I realize that is debatable, but there is where I come out." (JA532a-533a).

> administrative record alone and that, if so, such discovery would be unnecessary. We concluded, however, and so indicated to counsel, that plaintiffs were at the very least entitled to discovery to determine whether the record as filed was complete. At that time it was not known to counsel whether the Secretary would prepare and file formal findings. We therefore also indicated to the parties, in line with our interpretation of the Supreme Court's opinion, that plaintiffs should be allowed, in taking the discovery, to explore the mental processes of the agency people, including the Secretary, and that we would later decide to what extent such proof would be admissible at the hearing. The Secretary has never prepared and filed formal findings,[5] so, again in line with our interpretation of the Supreme Court's opinion, we admitted in evidence at the plenary hearing testimony having to do with the mental processes of the persons involved in making the decision, including the deposition of the Secretary.
>
> * * *
>
> We believe that it can fairly be said that the inquiry was substantial, thorough, probing, in-depth, searching and careful.
>
> ---
>
> [5] The Secretary filed an affidavit dated July 15, 1971 on July 22, 1971, but his counsel expressly stated, on inquiry from this Court, that such was not to be treated as formal findings within the meaning of the Supreme Court's opinion. *Citizens to Preserve Overton Park v. Volpe,* 335 F. Supp. 873 at 877-878 (W.D. Tenn. 1972)."

The approach taken in the *Overton Park* remand was clearly consistent with the Supreme Court's direction and was approved in *Maryland-National Capital Park v. United States Postal Service,* 487 F.2d 1029, 1041 n.13 (D.C. Cir. 1973). On the other hand, the approach taken by the District Court prevented a full inquiry into the true reasoning behind the agency's drug classification.[30]

30. This was further complicated by the agency argument below that the Commissioner was not changing his prior position as announced in the Federal Register of August 2, 1973 (JA547a). In fact, the lower court's opinion makes no reference to the earlier agency rationale and its invalidation by this Court.

The need for examination of the Commissioner under the almost unique circumstances of this case are clear. The Commissioner's affidavit completely failed to explain the relationship between the drug classification in the general vitamin regulations, which was invalidated, and the attempted drug classification in the instant proceeding. Also absent is any explanation of the method by which the precise levels of 10,000 I.U. and 400 I.U. were selected as drug levels. With respect to vitamin D, no explanation was made to justify retention of the very same threshold drug level which was invalidated by this Court as to the general vitamin regulations. With respect to vitamin A, the Commissioner failed to explain why 10,000 I.U. could be appropriate for drug classification despite the fact that an 8,000 I.U. level had been invalidated with respect to the other agency proceeding. The questions of therapeutic usage and promotion were left vague by recourse to such terms as "high dosages" and other generalizations. Inquiry most certainly should have been directed with respect to the fact that the Commissioner in his first affidavit purported to base his decision on materials which were not even in existence at the time the regulations were first promulgated. The inconsistencies between the first and second affidavits, as well as their total inconsistency with the Commissioner's own prior statement in the Federal Register of August 2, 1973, at the very least presented a serious issue of credibility which mandated a full examination for proper resolution.

As other courts have noted, *e.g., National Resources Defense Council, Inc. v. Train,* 519 F.2d at 287, 292 (D.C. Cir. 1975), appellants should have been entitled to conduct discovery at least to determine the proper scope of the administrative record. The Federal Register publications of the Commissioner made reference to various *ex parte* communications had by the agency in connection with the vitamin A and D regulations which to date have not been produced, even as part of the "voluntary" submissions in the District Court.[31] Although this Court found on the prior appeal that the record below was incomplete, the few documents which were produced were totally irrelevant to the question of drug classification and were not even cited in any respect in the lower court's opinion.

The need for a full review as to the true scope of the record is highlighted, however, by a few of these documents which indicated that, with respect to the proposed prescription level for vitamin D, the agency at one point seriously considered the raising of the level to 1,000 I.U. In the midst of these regulatory proceedings, the

31. See generally JA273a-275a.

agency undertook to unilaterally solicit by letter the opinions of various persons as to their views in this respect. (See Ja489a-494a.) No notice was ever given to the public of this solicitation of views and there was consequently no opportunity for the general public to argue in favor of a general increased limit for vitamin D. The result was that the agency permitted a 1,000 I.U. vitamin D product only where the product was designated to be for use under medical supervision. This alone constituted a serious departure from the notice requirements of the Administrative Procedure Act and constitutes a further indication of the haphazard manner in which the record herein was compiled.[32]

The position of the lower court seems to have been that the regulations could be upheld on the basis of an affidavit made by the Commissioner some two years after the regulations were promulgated, without any careful scrutiny or challenge by either counsel or the Court.[33] The comments of Judge Mansfield of this Court with respect to insuring of the integrity of the decision-making process of administrative agencies seem particularly appropriate.

> "Although an EIS may be supplemented, the critical agency decision must, of course, be made after the supplement has been circulated, considered and discussed in light of the alternatives, not before. Otherwise the process becomes a useless ritual, defeating the purpose of NEPA, and rather making a mockery of it." *Natural Resources Defense Council v. Callaway,* 524 F.2d 79 at 92 (2d Cir. 1975).

Similarly, Judge Bazelon recently cautioned:

> "A remand of the record alone can produce only a *post hoc* rationalization. . . . Such *post hoc* rationalizations have been consistently held to be inadequate to justify an otherwise vulnerable decision. The reason of this rule is that an agency

32. A further indication is the revelation that the articles in the medical literature supposedly relied on by the agency for the instant regulation, were not even part of the record before the Commissioner. Affidavits submitted in the District Court now reveal that copies of these articles were apparently not collected until after this action was commenced (JA281a, 373a).

"[A] document merely included on the bibliography . . ." (as was done in the instant case) "and not actually read by anyone in either agency would clearly not belong in the record." *Dry Colors Manufacturers Association, Inc. v. Department of Labor,* 486 F.2d 98 at 108, n. 16 (3d Cir. 1973).

33. Judge Frankel noted that various arguments were "pitched" against the affidavits, but did not discuss any of them (JA568a).

> might simply search for an explanation, in this case a distinction, to satisfy the requirement of a reasoned decision, regardless of whether the agency would have been genuinely impressed with the explanation or distinction if the matter were properly considered in the first instance. *The wisdom of this rule is particularly evident when the agency's error is the failure to give a 'hard look' in the first place." Local 814, Int. Bro. of Teamsters v. NLRB,* 512 F.2d 564, 572 (D.C. Cir. 1975). (Emphasis added.)

It is respectfully submitted that the ruling of the District Court as to the conduct of the remand proceedings and in denying appellants the opportunity to cross-examine the Commissioner resulted in a total absence of any meaningful developments in the remand proceedings. The record remained the very same which was originally before this Court and in effect, found insufficient to support the regulations. The affidavit submitted repeated, albeit in other forms, the very same rationale which was invalidated by this Court. The failure to allow cross-examination meant that in reality no *Overton*-type hearing was conducted.

B. The District Court Failed To Comply With The Direction Of This Court Which Required The Production Of The Entire Administrative Record.

As part of the prior appeal herein, the parties extensively briefed and argued the issue of the proper scope of the administrative record herein. This Court ruled that it had not "been furnished with the entire record that formed the basis of the FDA's classification." 512 F.2d at 702. This Court expressly directed the District Court to scrutinize the entire record in line with the ruling of the First Circuit in *Silva v. Lynn,* 482 F.2d 1282 (1st Cir. 1973). The question of the proper scope of the record in the context of judicial review of rule-making is inevitably crucial towards any judicial determination. In the face of this Court's ruling, the agency upon remand (JA373a) nevertheless insisted that the record which was previously before this Court was complete and needed no supplementation. In effect, the agency sought to reargue the decision of this Court (with ultimate success) in the District Court. This approach by the agency necessarily made the remand an exercise in futility. This Court, in effect, had already ruled that the unsupplemented record was insufficient to support the agency's drug classification.

Finally, at the conferences before Judge Frankel on May 28, 1976 and June 1, 1976, the agency relented in part and agreed to "voluntarily" produce some of the documents (JA51a) which it had located.[34] As already noted, the documents voluntarily submitted were in any event irrelevant to the issues raised in the remand proceeding.

The government insisted on, and the lower court sustained, the withholding of "some two dozen papers, all consisting of internal FDA memoranda or proposed drafts of the original notice." (JA569a). These were submitted to the Court and Judge Frankel examined them, not to ascertain their relevance to the issues presented, but only as to whether they were fairly and accurately characterized as intra-agency communications and prior drafts (JA579a, n.4).

Appellants respectfully submit that this Court previously ruled on this issue in applying the rule of *Silva v. Lynn, supra,* to the instant case, with respect to the nature of the record for review under the arbitrary and capricious tests. In that case, the First Circuit was faced with a situation very similar to that presented here. An administrative agency presented for judicial review a proposed environmental impact together only with the comments which had been filed in objection thereto. Here too, the agency is insisting that only the comments filed be considered the record for review.

The First Circuit, in *Silva v. Lynn, supra,* held at 482 F.2d 1283-1284:

> "In reviewing the final EIS and HUD's decision to proceed with the plan as described therein, the district court considered only the final statement, the draft statement and comments filed thereto, certain affidavits and testimony taken in court. It refused appellants' requests that the administrative record be produced. This record contains the more detailed studies *and background of deliberation which form the basis of the final EIS.* We think that the law requires production of the entire administrative record. . . [citations omitted].[1]
>
> Aside from the fact that this prerequisite to judicial review seems legally required, it makes good

34. No examination was allowed as to the proper scope of the record and government counsel expressly admitted that no assurance could be given that any of these documents had in fact been before the Commissioner when he promulgated the instant regulations (Conference of May 28, 1976, p. 6, lines 2-3, JA521a).

> practical sense . . . [U]ncertainty must attend a court's approval of a statement based on an unknown 'record of expert views and opinions, the technological data and other relevant material . . . on which the [agency] acted' but now refuses to supply . . . Moreover, to the extent that there is more than a perfunctory exchange of views incorporated in the record, *i.e.*, a reflection of comments not merely on a preliminary draft but on new approaches or evidence subsequently developed, the need for taking additional evidence in court diminishes. . . . *Finally, full disclosure is both a spur to reasoned decision making and a protection against criticism unfairly sought to be made after the agency's process have concluded.* [Emphasis added.]

[1] . . . While there may be some instances in which the entire record need not be filed, where the correctness of factual findings are involved or where the complainants request the full record, we think the agency must produce it in court."

By adopting this rule of law, this Court expressly indicated that the record herein was to consist of the entire "background of deliberation" in the instant case. See also, *Bradley v. Weinberger,* 483 F.2d 410 at 414, n. 4 (1st Cir. 1973). The documents withheld under the lower court's ruling, are part of this "deliberative background" and should have been included as part of the record. Inexplicably, the lower court makes no reference to *Silva v. Lynn, supra.*

The thrust of the government's objection to producing these documents consisted of a vague and non-specific general assertion of privilege with respect to the prior proposed drafts and certain "action memoranda" which presumably recommended promulgation of these regulations. The claim of privilege was asserted for the first time upon the remand by way of an affidavit of FDA counsel (JA375a).

It is respectfully submitted that the lower court seriously erred and departed from the well-developed and substantial case law in classifying these documents as "presumptively privileged" based on the exemption in the Freedom of Information Act contained in 5 U.S.C. §552(b)(5). The exemptions in the Freedom of Information

Act are not directly relevant to the instant case. Under such Act, if documents fall within one of the exempt categories, they are automatically exempt when sought by a party which is not in litigation with the United States. The courts have recognized this distinction in noting that Freedom of Information Act request must be treated on an abstract basis without reference to the specific needs of the parties requesting such documents. See, *e.g., EPA v. Mink,* 410 U.S. 73 at 85-87 (1973); *Kent Corp. v. NLRB,* 530 F.2d 612 at 624 (5th Cir. 1976). The District Court completely failed, however, to consider the requirements as developed in a long line of cases with respect to the assertion of a claim of executive privilege in a civil lawsuit such as the instant case.

Under Rule 26 of the Federal Rules of Civil Procedure, discovery is allowed of any relevant matter which is not privileged from disclosure. Traditionally, the courts have recognized varying degrees of "executive privilege" with respect to intra-agency advisory communications for the purpose of encouraging frank discussion within government in connection with the formulation of policy. See, generally, *United States v. Nixon,* 418 U.S. 683 (1974). The privilege is limited, however, and does not attach to any documents involving purely factual communications and where factual material is contained as part of deliberate memoranda, the courts have required that such material be severed and made available to the appropriate parties. *EPA v. Mink, supra.*[35]

Even with respect to documents covered, the privilege is far from absolute. *United States v. Nixon, supra.* The burden of asserting any privilege should be on the party claiming an exemption from disclosure. Under the case law, three requirements have emerged for the proper support of a claim of executive privilege. First, the privilege must be claimed by the head of the applicable agency who has personally considered and affirmed the need for the invocation of the privilege. *United States v. Reynolds,* 345 U.S. 1 at 7-8 (1953). Secondly, the courts require a specific designation and description of the douments which are claimed to be privileged. See, *e.g., Black v. Sheraton Corp. of America,* 371 F. Supp. 97 (D. D.C. 1974). In addition, the case law requires that the governmental official present a clear explanation of why it is necessary to withhold the documents at issue for the purpose of preserving the confidentiality of governmental communications. All of these showings have generally been required in the form of an affidavit by

35. An excellent summary of the development of the case law with respect to executive privilege can be found in a lower court decision in *Smith v. FTC,* 403 F. Supp. 1000 at 1014-1016 (D. Del. 1975).

the appropriate head of the agency involved.[36] None of these requirements were complied with herein. See generally, *Amchem Products Inc. v. GAF Corp. & Train,* 64 F.R.D. 550 at 553-554 (N.D. Ga. 1974); *United States v. 30 Jars More or Less v. "Ahead Hair Restorer",* 43 F.R.D. 181 at 190 (D. Del. 1967); *Thill Securities Corp. v. N.Y. Stock Exchange,* 57 F.R.D. 133 (D. Wis. 1972); 8 Wright & Miller, Federal Practice and Procedure, Civil §2019 (1970).

Essentially, any claim of governmental privilege involves an *ad hoc* balancing of the litigants' need for the materials as against the specific harm to governmental functions which might result from such a disclosure. *EPA v. Mink, supra; United States v. Reynolds, supra; Black v. Sheraton, supra; SEC v. Bausch & Lomb Co.,* 19 Fed. Rules Service 2d 332 (S.D.N.Y. 1974). Unfortunately, the District Court does not discuss these criteria specifically nor their applicability to the instant case.

The District Court felt that the requirements of judicial review did not necessitate the inclusion of these documents in the "record." (JA570a). It is respectfully submitted that many cases are to the contrary. As already noted, the First Circuit in *Silva v. Lynn, supra,* and *Bradley v. Weinberger, supra,* expressly directed the incorporation of deliberative background material as part of the "record" where the applicable standard for judicial review was "arbitrary, capricious or otherwise not in accordance with law" standard. The types of documents which were withheld by the agency herein have very often figured prominently in judicial review of agency action.[37] In fact, agencies very frequently have made recourse to these internal memoranda for the purpose of sustaining what might otherwise be invalid agency action. See, *e.g., Dry Color Manufacturers Association Inc. v. Department of Labor,* 486 F.2d 98 at 108-109 (3d Cir. 1973) [agency sought to rely on summaries

36. The District Court was advised of these general criteria, but makes no reference to them in its formal opinion. (See JA544a, 551a.)

37. See, *Aguayo v. Richardson,* 473 F.2d 1090 at 1105 (2d Cir. 1973) [court relying on action memoranda which were included in record]; *Hanly v. Mitchell,* 460 F.2d 640 at 645-646 (2d Cir. 1972) [deliberative memorandum of Assistant Commissioner deemed crucial to decision on appeal]; *Named Ind. Mem. of San Antonio Conservation Society v. Texas Highway Department,* 446 F.2d 1013 at 1027-1028 (5th Cir. 1971) [review of internal memoranda results in reversal for remand]; *Appalachian Power Co. v. EPA,* 477 F.2d 495 at 507 (4th Cir. 1973) [court requires opinions before agency is to be included in record]; *GTE Sylvania Inc. v. Consumer Product Safety Commission,* 404 F. Supp. 352 at 368-369 (D. Del. 1975) [court relies on intra-agency "Cull Memorandum" in reaching decision to issue preliminary injunction]; *Scientists' Institute for Public Information Inc. v. AEC,* 481 F.2d 1079 at 1095 (D.C. Cir. 1973) [court considers records compiled in District Court which included in large part analyses and reports prepared by Commission]; *State of Delaware v. Bender,* 402 F. Supp. 1066 at 1072-1073 (D. Del. 1975) [court relies on internal letter as well as file from District Commander].

and recommendations over objections of industry]; *Upper W. Fork River Water Shed v. Corps of Engineers,* 414 F. Supp. 908 at 913-914 (N.D. W.Va. 1976) [court refuses to strike various internal deliberative memoranda from record].

Thus, in *GTE Sylvania Inc. v. Consumer Product Safety Commission,* 404 F. Supp. 352 at 368, n.67 (D. Del. 1975):

> "The 'record' here encompasses more than the materials contained in the Commission's purported official record. Internal Commission memoranda and even plaintiffs' communications to the Commission can be examined to determine if the Commission should have been aware of certain issues."

Along the same lines, an administrative agency record subject to review under the arbitrary and capricious standard, was found to be insufficient in *Natural Resources Defense Council, Inc. v. Train,* 519 F.2d 287 at 292 (D.C. Cir. 1975), because internal agency documents had not been included as part of the record. The Court stated:

> "The report contains a detailed discussion of the issues before the Administrator, factual data, analysis of proposed listings and screening criteria, and recommendations. Plainly, the document throws light on the factors and considerations relied upon by the Administrator . . . ." *Id.* at 292.

As noted by Judge Lumbard in concurring on the prior appeal in this case, the courts should adapt procedural rules in terms of the requirements of judicial review of rule-making, 512 F.2d at 705. The courts have now, often limited the scope of judicial review to the "arbitrary, capricious and otherwise not in accordance with law" standard to the extent where this Court has indicated that an agency upon such review may even rely upon information contained in its files. *Consumers Union of U.S., Inc. v. Consumer Product Safety Commission,* 491 F.2d 810 at 812 (2d Cir. 1974). As the previously cited cases indicate, agencies will often not hesitate to make use of this particular factor in seeking to sustain agency action. Concomitantly, the courts should require that these internal documents should also be disclosed, at least upon request, for the potential purpose of invalidating agency action. The applicable standard of review requires the courts to consider whether the agency properly took into account all of the relevant factors. At the same time, judicial review must ascertain that the agency did not

consider impermissible factors at arriving at a decision. The inclusion of these internal memoranda in the record, is now, therefore, essential in order to insure that judicial review is not frustrated. See *Smith v. F.T.C., supra,* at 403 F. Supp. 1008-1009.[38]

The Court should also consider that the vague invocation of executive privilege in the instant case is reflective of the lack of any prejudice in fact accruing to an agency in these circumstances from disclosure of documents such as the ones withheld herein. In *Community Savings and Loan Association v. Federal Home Loan Bank Board,* 68 F.R.D. 378 (E.D. Wis. 1975), the Court took note with respect to a claim virtually identical to the one raised by the agency herein, that a long line of cases had shown that disclosure of the documents in question was not prejudicial to the agency.

> "Despite these cases, there has been no claim that the Comptroller of the Currency suffers from a lack of open and honest discussion regarding the decisions which that agency should reach. In light of this situation, this Court does not believe that any ill effects will result from allowing plaintiffs to see the information in question." *Id.* at 382.

With respect to the FDA, it should be noted that in at least one instance, as far as appellants are aware, agency memoranda and prior drafts of the exact type which are at issue herein, were included in a record filed with this Court. *Consumers Union of U.S., Inc. v. Consumer Product Safety Commission, supra* (JA624a-631a).[39]

Moreover, the agency itself is not averse on occasion to releasing these types of documents to the public. As recently as October 19, 1976, the same Commissioner for the same agency released to the public such an internal agency memoranda in connection with the finalized general vitamin regulations:

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38. In response to an argument similar to that raised by the agency herein, the Court noted:

> "However, such a position cannot be maintained because one of the many bases which justify the 'substantial' nature of this type of judicial inquiry is to determine if any impermissible factors have entered into an agency's reasoning process." *Smith v. FTC, supra,* at 1009. See also textual material accompanying n. 23. *Id.*

39. The documents involved were originally FDA documents prior to a change in delegation of responsibility to a new agency in the midst of judicial review. See Copy of certified record on appeal taken from the records of this Court and which are set forth at JA629a.

> "On April 29, 1976, the FDA Bureau of Foods Assistant Associate Director for Nutrition and Consumer Sciences forwarded to the Acting Associate Director a report on the 'Applications for Additional Dietary Supplement Formulations.' The report considered all submissions that had been received (including some submissions received after the August 29, 1975, deadline), and it recommended that eight additional formulations be authorized.
>
> * * *
>
> However, because the Commissioner believes that the report prepared by the Assistant Associate Director for Nutrition and Consumer Sciences may be useful to the public, the Commissioner has determined to make it available. As an intra-agency memorandum making recommendations for action by the FDA, this document would not be required to be disclosed under the Freedom of Information Act. However, in the exercise of his discretion, the Commissioner has forwarded a copy of the document to the office of the Hearing Clerk, Food and Drug Administration, where it will be available for public scrutiny; copies may be requested at cost. (The report is not an official statement of FDA policy; indeed, the Commissioner might not have accepted its recommendations. *Yet, as a comprehensive review of a controversial matter by informed agency staff, it should be of interest and use to the public.*" (Emphasis added.) Federal Register, Oct. 19, 1976, pp. 46156-46157.

Apparently, it is the policy of the agency to release these documents at its discretion while at the same time seeking to deny them in circumstances where they may be of utility to litigants in a position adverse to the agency. It is respectfully submitted that this Court should not countenance this type of double-standard.

Although appellants respectfully submit that the withheld documents by their nature should generally be included in all agency records which are submitted for judicial review, the inclusion here is particularly appropriate and required in light of the tortured history and background of these regulations. In circumstances where the agency expresses a rationale, which is invalidated by this Court, the judicial search for the truth must be hampered if the same agency is

allowed to present new affidavits of explanation without being required to disclose these relevant internal memoranda.

> "The doctrine of privilege contains the potential for misuse. *Carr v. Monroe Manufacturing Co.*, 431 F.2d 384 (5th Cir. 1970), *cert. denied*, 400 U.S. 1000, 91 S. Ct. 456, 27 L.Ed.2d 451 (1971). The secrecy protected by the privilege can be used to cover up mischievous conduct or incompetency. *In a case like the present, where the agency has completely changed its position on an application within a relatively short period of time, public confidence in the soundness of the decision-making process will be promoted by allowing plaintiffs to see the information they request.*" (Emphasis added.) *Community Savings and Loan Association v. Federal Home Loan Bank Board, supra,* at 382.

Public confidence and efficient judicial administration are not fostered by the arbitrary withholding of documents in the instant case. Interestingly enough, Judge Frankel recognized this aspect and attempted to induce counsel for the government to make these documents available without success.[40]

40.

"THE COURT: . . .How many papers are we talking about? You are holding up an envelope about an inch and a half thick?

MS. BUCHWALD: Right.

THE COURT: If that sheaf of papers were handed to Mr. Bass to read in conjunction with his attack on your vitamin A and D regulations, would it affect any considerations of privacy or security that are important?

The reason I ask that is this: If I have to make a decision in advance of deciding this case as to what constitutes a record, for good and sufficient reason I will do it. On the other hand, if I don't and I allow some things to be disclosed to Mr. Bass that, strictly speaking, are not part of the record, and he exploits them, then it seems to me the Court of Appeals will have the whole business in one fell swoop, and if these things were given to him erroneously, whatever mistaken result that has they can fix. If they were withheld from him erroneously, they can't fix it; they have to send it back here. And, as much as I love seeing you both, one more remand of this would be one more remand than I really need.

If you gave him that stuff without prejudice, just understanding that it was in the support of a trial judge's effort to expedite the work, would the FDA be hurt?" (JA521a-522a).

"Tell the people in your agencies that fighting about these details is not a fruitful use of their time or mine." (JA527a).

Unfortunately, the District Court did not even examine the withheld material from a substantive point of view to determine its relevance in terms of a drug classification. Even such a proper examination could not be a substitute for thorough analysis by counsel. The withholding of these documents, coming after the "voluntary" submission of some pieces of paper which proved to be irrelevant, almost inescapably gives rise to a strong inference that the withheld documents may contain information adverse to the agency's position. To the extent that any legitimate privacy factors are involved in the disclosure of these documents, an appropriate protective order could have been entered. See, *e.g., Charles River Park v. HUD,* 519 F.2d 935 at 943 (D.C. Cir. 1975) (confidentialty requirement imposed).

The blanket failure to produce the documents at issue for proper consideration by the parties and the Court further serves to re-emphasize the insufficiency of the remand proceedings and the total failure by the agency to demonstrate any proper basis for drug classification herein.

CONCLUSION

For all of the foregoing reasons, plaintiffs-appellants respectfully submit that the decision of the District Court should be reversed.

Respectfully submitted,

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Milton A. Bass
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ADDENDUM

REGULATIONS UNDER REVIEW

21 C.F.R. §250.109 Vitamin A preparations for oral use as drugs.

(a) Vitamin A is an essental nutrient for humans. It is widely recognized that large amounts of vitamin A can cause adverse effects, some of which are serious. The U.S. Recommended Daily Allowance (U.S. RDA) for vitamin A is 1500 International Units, (IU) for infants, 2500 IU for children under 4 years of age, 5000 IU for adults and children 4 or more years of age, and 8000 IU for pregnant or lactating women.

(b) In view of the toxicity of excessive consumption of vitamin A, the Food and Drug Administration finds that, in order to protect the public health, oral preparations containing vitamin A in excess of 10,000 IU per dosage unit or recommended daily intake are drugs subject to section 503(b)(1) of the Federal Food, Drug, and Cosmetic Act and shall be restricted to prescription sale. Such products will be regarded as misbranded if at any time prior to dispensing the following conditions are not met:

(1) The label bears the legend, "Caution: Federal law prohibits dispensing without a prescription"; and

(2) The labeling bears full disclosure information as required by § 201.100(c)(1) of this chapter, and especially appropriate warnings regarding vitamin A toxicity.

(c) Preparations containing 10,000 or less IU of vitamin A per dosage unit will be regarded as misbranded if their recommended daily intake exceeds 10,000 IU.

(Secs. 502(a), (f), and (j), 503(b), 701(a), 52 Stat. 1050–1052, as amended, 1055; 21 U.S.C. 352(a), (f), and (j), 353(b), 371(a))

§ 250.110 Vitamin D preparations for oral use as drugs.

(a) Vitamin D is an essential nutrient for humans. It is widely recognized that vitamin D, when ingested daily in large amounts, is toxic. The U.S. Recommended Daily Allowance (U.S. RDA) for vitamin D is 400 International Units (IU).

(b) In view of the toxicity of the excessive consumption of vitamin D, the Food and Drug Administration finds that, in order to protect the public health, oral preparations containing vitamin D in ex-

cess of 400 IU per dosage unit or recommended daily intake are drugs subject to section 503(b)(1) of the Federal Food, Drug, and Cosmetic Act and shall be restricted to prescription sale. Such products will be regarded as misbranded if at any time prior to dispensing the following conditions are not met:

(1) The label bears the legend, "Caution: Federal law prohibits dispensing without a prescription"; and

(2) The labeling bears full disclosure information as required by § 201.100(c)(1) of this chapter, and especially appropriate warnings regarding vitamin D toxicity.

(c) Preparations containing 400 or less IU of vitamin D per dosage unit will be regarded as misbranded if their recommended daily intake exceeds 400 IU.

(d) Foods which are represented for use solely under medical supervision to meet nutritional requirements of persons with poor vitamin D absorption may contain vitamin D not in excess of 1000 IU per dosage unit or recommended daily intake.

RELEVANT STATUTES

21 U.S.C. §321(g)(1)

FEDERAL FOOD, DRUG, AND COSMETIC ACT, AS AMENDED

DEFINITIONS

Section 201(g)(1) [21 USC 321(g)(1)]. The term "drug" means (A) articles recognized in the official United States Pharmacopeia, official Homeopathic Pharmacopeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any articles specified in clause (A), (B), or (C); but does not include devices or their components, parts, or accessories.

21 U.S.C. §342 Adulterated Food

A food shall be deemed to be adulterated—

Poisonous, insanitary, etc., ingredients

(a) (1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health; or (2) (A) if it bears or contains any added poisonous or added deleterious substance (other than one which is (i) a pesticide chemical in or on a raw agricultural commodity; (ii) a food additive; (iii) a color additive; or (iv) a new animal drug) which is unsafe within the meaning of section 346 of this title, or (B) if it is a raw agricultural commodity and it bears or contains a pesticide chemical which is unsafe within the meaning of section 346a(a) of this title, or (C) if it is, or it bears or contains, any food additive which is unsafe within the meaning of section 348 of this title: *Provided*, That where a pesticide chemical has been used in or on a raw agricultural commodity in conformity with an exemption granted or a tolerance prescribed under section 346a of this title and such raw agricultural commodity has been subjected to processing such as canning, cooking, freezing, dehydrating, or milling, the residue of such pesticide chemical remaining in or on such processed food shall, notwithstanding the provisions of sections 346 and 348 of this title, not be deemed unsafe if such residue in or on the raw agricultural commodity has been removed to the extent possible in good manufacturing practice and the concentration of such residue in the processed food when ready to eat is not greater than the tolerance prescribed for the raw agricultural commodity, or (D) if it is, or it bears or contains, a new animal drug (or conversion product thereof) which is unsafe within the meaning of section 360b of this title; or (3) if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; or (4) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; or (5) if it is, in whole or in part, the product of a diseased animal or of an animal which has died otherwise than by slaughter; or (6) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or (7) if it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to section 348 of this title.

Absence, substitution, or addition of constituents

(b) (1) If any valuable constituent has been in whole or in part omitted or abstracted therefrom; or (2) if any substance has been substituted wholly or in part therefor; or (3) if damage or inferiori-

ty has been concealed in any manner; or (4) if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is.

Color additives

(c) If it is, or it bears or contains, a color additive which is unsafe within the meaning of section 376(a) of this title.

Confectionery containing alcohol or nonnutritive substance

(d) If it is confectionery, and—

(1) has partially or completely imbedded therein any nonnutritive object: *Provided,* That this clause shall not apply in the case of any nonnutritive object if, in the judgment of the Secretary as provided by regulations, such object is of practical functional value to the confectionery product and would not render the product injurious or hazardous to health;

(2) bears or contains any alcohol other than alcohol not in excess of one-half of 1 per centum by volume derived solely from the use of flavoring extracts; or

(3) bears or contains any nonnutritive substance: *Provided,* That this clause shall not apply to a safe nonnutritive substance which is in or on confectionery by reason of its use for some practical functional purpose in the manufacture, packaging, or storage of such confectionery if the use of the substance does not promote deception of the consumer or otherwise result in adulteration or misbranding in violation of any provision of this chapter: *And provided further,* That the Secretary may, for the purpose of avoiding or resolving uncertainty as to the application of this clause, issue regulations allowing or prohibiting the use of particular nonnutritive substances.

Oleomargarine containing filthy, putrid, etc., matter

(e) If it is oleomargarine or margarine or butter and any of the raw material used therein consisted in whole or in part of any filthy, putrid, or decomposed substance, or such oleomargarine or margarine or butter is otherwise unfit for food.

Section 411, 21 U.S.C. §350. Vitamins and minerals—Authority and limitations of Secretary; applicability

(a)(1) Except as provided in paragraph (2)—

(A) the Secretary may not establish, under section 321n, 341, or 343 of this title, maximum limits on the potency of any synthetic or natural vitamin or mineral within a food to which this section applies;

(B) the Secretary may not classify any natural or synthetic vitamin or mineral (or combination thereof) as a drug solely because it exceeds the level of potency which the Secretary determines is nutritionally rational or useful;

(C) the Secretary may not limit, under section 321n, 341, or 343 of this title, the combination or number of any synthetic or natural—

(i) vitamin,
(ii) mineral, or
(iii) other ingredient of food,

within a food to which this section applies.

(2) Paragraph (1) shall not apply in the case of a vitamin, mineral, other ingredient of food, or food, which is represented for use by individuals in the treatment or management of specific diseases or disorders, by children, or by pregnant or lactating women. For purposes of this subparagraph, the term "children" means individuals who are under the age of twelve years.

Labeling and advertising requirements for foods

(b)(1) A food to which this section applies shall not be deemed under section 343 of this title to be misbranded solely because its label bears, in accordance with section 343(i)(2) of this title, all the ingredients in the food or its advertising contains references to ingredients in the food which are not vitamins or minerals.

(2)(A) The labeling for any food to which this section applies may not list its ingredients which are not vitamins or minerals (i) except as a part of a list of all the ingredients of such food, and (ii) unless such ingredients are listed in accordance with applicable regulations under section 343 of this title. To the extent that compliance with clause (i) of this subparagraph is impracticable or results in deception or unfair competition, exemptions shall be established by regulations promulgated by the Secretary.

(B) Notwithstanding the provisions of subparagraph (A), the labeling and advertising for any food to which this section applies may not give prominence to or emphasize ingredients which are not—

(i) vitamins,
(ii) minerals, or
(iii) represented as a source of vitamins or minerals.

Definitions

(c)(1) For purposes of this section, the term "food to which this section applies" means a food for humans which is a food for special dietary use—

(A) which is or contains any natural or synthetic vitamin or mineral, and

(B) which—

(i) is intended for ingestion in tablet, capsule, or liquid form, or

(ii) if not intended for ingestion in such a form, does not simulate and is not represented as conventional food and is not represented for use as a sole item of a meal or of the diet.

(2) For purposes of paragraph (1)(B)(i), a food shall be considered as intended for ingestion in liquid form only if it is formulated in a fluid carrier and it is intended for ingestion in daily quantities measured in drops or similar small units of measure.

(3) For purposes of paragraph (1) and of section 343(j) of this title insofar as that section is applicable to food to which this section applies, the term "special dietary use" as applied to food used by man means a particular use for which a food purports or is represented to be used, including but not limited to the following:

(A) Supplying a special dietary need that exists by reason of a physical, physiological, pathological, or other condition, including but not limited to the condition of disease, convalescence, preg-

nancy, lactation, infancy, allergic hypersensitivity to food, underweight, overweight, or the need to control the intake of sodium.

(B) Supplying a vitamin, mineral, or other ingredient for use by man to supplement his diet by increasing the total dietary intake.

(C) Supplying a special dietary need by reason of being a food for use as the sole item of the diet.

CERTIFICATE OF SERVICE

Docket No. 76-6135
Re: National Nutritional Foods v
Mathews

STATE OF NEW JERSEY :
: ss.:
COUNTY OF MIDDLESEX :

I, Muriel Mayer, being duly sworn according to law, and over the age of 21 upon my oath depose and say that: I am r by the attorney for the above named Plaintiffs-Appellants.

That on the 10th day of November, 1976, I served the wit

Brief of Plaintiffs-Appellants

in the matter of National Nutritional Foods Assoc. & Solgar David F. Mathews

upon

Robert B. Fiske, Jr., Esq.
United States Attorney for Second Circuit
Att: Naomi R. Buchwald, Esq.
1 St. Andrews Plaza, New York, New york 10007

by depositing two (2) true copies of the same securely enc in a post-paid wrapper, in an official depository maintained United States Government.

Muriel Mayer
Muriel Mayer

Sworn to and subscribed
before me this 10th day
of November 1976.

L. Lotta